

Amendment and Response Under 37 C.F.R. §1.116 - Expedited Examining Procedure

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Serial No.: 09/727,739

Confirmation No.: 4181

Filed: December 1, 2000

For: SOMATOSTATINS AND METHODS

Remarks

The Final Office Action mailed January 13, 2003 has been received and reviewed. Applicants acknowledge, with appreciation, the withdrawal of the objection to the disclosure, as set forth at page 3, in the previous Office Action dated June 28, 2002. Applicants also acknowledge, with appreciation, the withdrawal of the rejection of claims 1 and 2 under 35 U.S.C. §101, as set forth at page 3, and the rejection of claims 1, 12, and 13 under 35 U.S.C. §112, first paragraph, as set forth at pages 3-5.

Claims 7-11 having been canceled, and claims 3 and 4 having been amended, the pending claims are claims 1-6 and 12-15. Of these, claims 4-6 have been withdrawn from examination by the Examiner, and claims 1-3 and 12-15 are presently under examination.

The 35 U.S.C. §101 Rejection

The Examiner's rejection of claim 3 under 35 U.S.C. §101, relating to nonstatutory subject matter, set forth at page 3 of the Office Action mailed June 28, 2002, was maintained. Claim 3 has been amended to recite an "isolated or purified" polypeptide. Applicants intended to make this amendment in the Amendment mailed October 28, 2002 and apologize for the oversight. It is respectfully submitted that the amendment to claim 3 obviates this rejection. Reconsideration and withdrawal of the rejection of claim 3 under 35 U.S.C. §101 is respectfully requested.

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Claim Objections

The objection to claims 1-3 and 12-14 for minor informalities was maintained. The Examiner contends that the amended claims recite unelected subject matter, namely SEQ ID NOs:2, 16, 17 and 19.

This rejection is respectfully traversed. At paragraph 1 of the Restriction Requirement mailed October 4, 2001, the Examiner identified three inventions:

- I. Claims 1-3 and 12-15, drawn to somatostatin polypeptides
- II. Claims 4-6, drawn to polynucleotides
- III. Claims 7-11, drawn to a method of identifying a modified somatostatin polypeptide.

Applicants elected invention I, claims 1-3 and 12-15.

At paragraph 8 of the Restriction Requirement, the Examiner identified three patentably distinct species of the claimed invention, identified herein as A, B and C for ease of reference, as follows:

- A. Corresponding to PPSS-I: SEQ ID NO:8 (a nucleotide sequence) encoding SEQ ID NO:3 (a polypeptide sequence)
- B. Corresponding to PPSS-II': SEQ ID NO:14 (a PPSS-II' nucleotide sequence) encoding SEQ ID NO:9 (a polypeptide sequence)
- C. Corresponding to PPSS-II'': SEQ ID NO:20 (a nucleotide sequence) encoding SEQ ID NO:15 (a polypeptide sequence)

The Examiner stated: "Applicant is required under 35 U.S.C 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no

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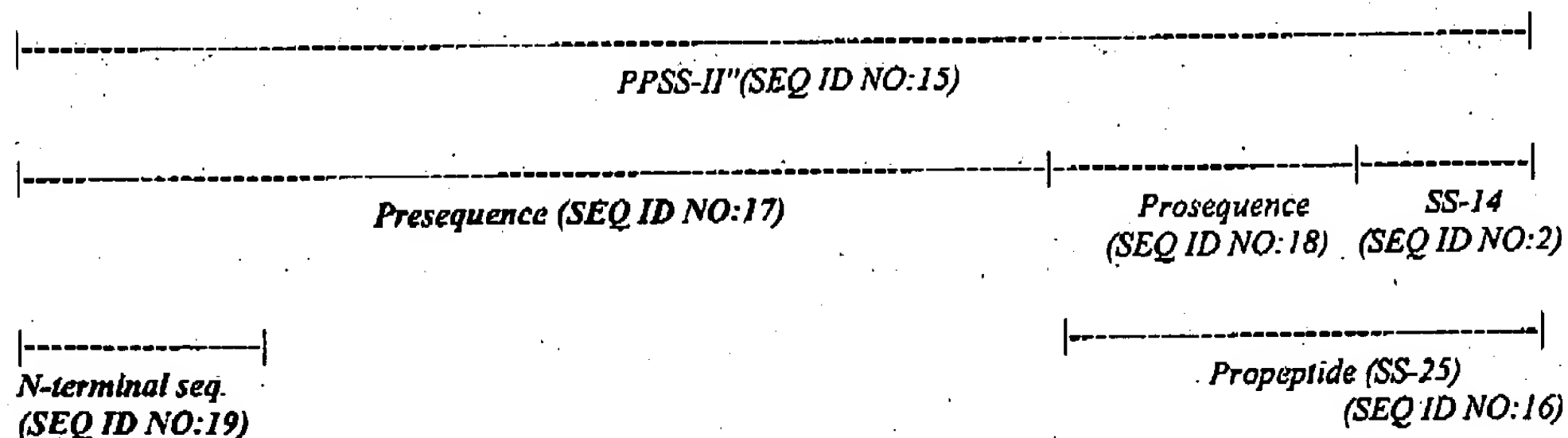
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generic claim is finally held to be allowable." The Restriction Requirement continues by advising the Applicant of his rights upon the allowance of a generic claim. Applicants properly responded to the requirement by electing species C (including SEQ ID NO:15) and providing a list of all claims readable thereon (i.e., claims 1-15, as originally filed), indicating that claims 1-15 were generic.

The Examiner is requested to note that, in order to further prosecution and in deference to the search burdens presently being experienced by the Office, Applicants *did amend the claims (without prejudice) to delete recitation of species A and B*, even though it is Applicants' understanding that such amendment was not required as the Examiner is under an obligation to consider these other two species if a generic claim is allowed. See the Applicants' Amendment submitted October 28, 2002.

What is presently at issue is the recitation in the claims of *subsequences* of elected amino acid sequence SEQ ID NO:15. Please note that these subsequences (i.e., SEQ ID NOs:2, 16, 17, 18 and 19) were not the subject of the Restriction Requirement or the species election. To assist the Examiner in understanding the relationships among these sequences, the following diagram is provided:

Invention I (somatostatin polypeptide)/Species C (SEQ ID NO:15)



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As noted, SEQ ID NOs: 2, 16, 17, 18 and 19 are subsequences of elected sequence SEQ ID NO:15 and were not the subject of the Restriction Requirement or species election, thus the Examiner should have searched and Examined these sequences in the present prosecution. Applicants understand the search burden on the Examiner but further point out that in order to fully assess the patentability of independent claims 1 and 3 (and thus those dependent from claim 1, namely claims 2 and 12-15), *only subsequences SEQ ID NOs: 17 and 19 (in bold in the above diagram) still need to be searched* (if they have not already been searched). It is respectfully submitted that searching SEQ ID NOs: 17 and 19 does not represent significant additional burden to the Examiner or the Office in view of the search and examination of SEQ ID NOs: 15 and 18 already performed. Please note that SEQ ID NOs: 2 and 16 do not need to be separately searched as they are taught in prior art already made of record by the Applicants (see e.g., salmon SS-14 (II) and SS-25 (II) in Table 2 in Sheridan et al., Amer. Zool. 40:269-286 (2000), citing Plisetskaya et al., (1986)).

Request for Modification of the Restriction Requirement

Applicants respectfully request modification of the restriction requirement to combine elected Group I (claims 1-3 and 12-15, drawn to somatostatin polypeptides) and nonelected Group II (claims 4-6, drawn to polynucleotides). Claims 4 and 5 are drawn to polynucleotides encoding the polypeptide of claim 1. Since claim 1 is free of the prior art, it is submitted that claims 4 and 5 (directed to polynucleotides encoding the polypeptide of claim 1) are also free of the prior art and can be readily examined with the presently elected claims. Claim 6 is directed to a polynucleotide that is substantially complementary to the polynucleotide of claim 4 and could therefore also be readily examined in the present prosecution.

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It is respectfully submitted that the pending claims 1-6 and 12-15 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
Sheridan et al.

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PATENT TRADEMARK OFFICE

March 18, 2003
Date

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that this paper is being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Assistant Commissioner for Patents, Box AF, Washington, D.C. 20231, on this 18 day of MARCH, 2003, at 1:50 pm (Central Time).

By: SAM HER
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